# Exhibit 14-2

State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc. et al., Civil Action No. 03-11226-PBS

Exhibit to the November 25, 2009 Declaration of Philip D. Robben in Support of Defendants' Joint Motion for Partial Summary Judgment

#### CHAPTER III

#### PROBLEMS AND ALTERNATIVES

Medi-Cal's price controls are ceiling prices. They specify for each drug controlled the maximum price the State will pay. It is likely that the initial impact of such controls was to reduce prices to levels below those that would have obtained in their absence. As time passed, pharmacists began to adjust to the controls in ways that probably were not expected. The Department of Health has not officially estimated savings arising from price controls. The relevant question at this point is whether additional savings can be had. In this chapter the effects of existing controls are examined, and alternative means of price control explained. Some alternatives are examined only briefly because of their complexity, or lack of experience with the alternative, or difficulty in evaluating programs, such as government ownership of pharmacies, many of whose costs and benefits are extrinsic to drug price control as such. The most promising alternative, and the one providing most insight into the nature of price control, is purchase at the lowest market prices. Chapters IV and V develop that alternative.

# Problems Arising from Controls Upon Ingredient Prices

Ceiling prices are not well adapted to coping with the great number of differences among providers. Attempts to achieve large additional savings by further reduction of fee or ingredient cost maxima are likely to be difficult to implement.

### Finding:

Medi-Cal's ceilings on the ingredient portion of its payments for drugs are well above the average price paid by pharmacies, but problems inherent in ceiling price controls prevent their being lowered.

- 1. The average wholesale price at which most drug ceilings are set is estimated to be 15 to 18 percent above the average price paid by pharmacies.
- "Average purchase price" is probably impossible to define and measur 2. The apparent principle upon which ingredient price control is based that the State pays cost. But if by cost is meant the "actual" pric paid by the pharmacists, it can only be identified in the obvious sense that individual invoice prices can be identified. The range o prices available to the pharmacist for a single drug differs greatly among pharmacists and among geographic areas, and changes rapidly. Even the concept of actual price is unclear because wholesalers' discounts usually apply to a month's purchases, and rebates, seasonal deals, extended credit terms and liberal returns policies substantial affect pharmacists' cost of operation, but do not always lend themsel to drug-by-drug cost determination. AWP, upon which most controls ar based, is readily identified. But it exceeds average purchase price perhaps 15 to 18 percent. For a given drug at a given point in time, may closely approximate cost, or exceed it by 50 percent or more. The order of magnitude estimates are made here because they are useful and represent a consensus even though "average purchase price" remains undefined.
- 3. <u>DOH's recent reduction in ceilings of some drugs to prices charged</u>

  <u>pharmacies who buy direct from manufactureres reflects an economy</u>

  <u>available to some pharmacies but not others</u>. The Estimated Acquisition

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Cost (EAC) program illustrates the difficulties in trying to strike more closely at actual acquisition cost, while retaining ceiling prices as the control principle. It was found that a large percentage of pharmacists buy direct from certain manufacturers most of the time, and that they buy certain drugs in quantities in excess of 100 per bottle most of the time. Therefore, DOH limited its compensation for drugs manufactured by 11 pharmaceutical manufacturers to the direct price charged by those manufacturers, and for 11 drugs to the 500 or 1,000 price per bottle. A key assumption of this approach is that, whether or not pharmacists purchase at the ceiling price, they ought to be able to do so if their business were properly managed. That assumption is is not supported by the data gathered by DOH to justify the EAC regulations. Some pharmacists buy in small quantities and buy from wholesalers because it is, net, more advantageous for them to do so.

4. Some manufacturers maximize pharmacy earnings from Medi-Cal by maximizing the spread between the price charged Medi-Cal (usually based on small quantities) and that paid by pharmacies (often a lower price based on large quantities). The requirement that Medi-Cal pay the 100 quantity price for tablets and capsules, except for the 11 EAC drugs, has permitted some small manufacturers to generate price lists specifically designed to maximize the spread between the 100 and 1,000 price in order to maximize their pharmacy customers' gross margin on Medi-Cal business. The Department of Health must set its price ceilings at a very high 100 price in order to accomodate pharmacies whose volume is not great enough to justify purchase of more than 100. But many pharmacies can buy at a very competitive 1,000 price. This distortion of normal pricing practice is a product solely of Medi-Cal price controls.

<sup>1/</sup>Hearings and Supporting Documents, DOH, December 27, 1976.

- 5. Pharmacies and manufacturers with large Medi-Cal sales tend to ra their prices to the ceiling level. The purpose of ceiling prices to generate savings by eliminating prices at the high end of a rai in the expectation that prices below the ceiling will remain unchanged. In fact, the 272 pharmacies who do \$100,000 or more of business per year with Medi-Cal, which amounts to more than one-third of Medi-Cal payments to pharmacies, almost invariably follow a policy of pricing at the Medi-Cal maxima. The net effect this practice can be, for those stores, an increase in net cost to Medi-Cal rather than the expected decrease if many prices are raise to the Medi-Cal maxima. This price behavior is documented in Chapter IV. The prices of some small generic manufacturers whose products are heavily used by Medi-Cal providers also tend to rise t the Maximum Allowable Ingredient Cost (MAIC) maxima.
- (MAIC) is limited by the requirement that the drug upon which the price is based be "widely" available. The Maximum Allowable Ingredient Cost (MAIC) program entails establishment of the ceiling price for a generic drug category at the price of the manufacturer whose price is lowest, provided that the product is widely available and of acceptable quality. In fact, many manufacturers sell drugs at and the State pays prices below MAIC maxima. This is due in part to the fact that practically all drugs can be bought at prices below AWP. But in addition, MAIC maxima cannot be set at prices of those many manufacturers whose products are likely to be available only temporarily, or in certain localities, or with an unacceptable delay.

High level of provider abuse is in part due to complex and 7. arbitrary controls. Early in 1977, pharmacies were overbilling Medi-Cal at a rate of more than \$600,000 per year. This amount was expected to increase to a rate of more than \$1 million discoverable by the Drug Utilization Review Unit (DURU) of DOH, whose function it is to determine, by onsite review, the extent of pharmacy providers' noncompliance with Medi-Cal regulations. DURU estimates that the annual rate of abuse is actually \$8 million or more, identifiable if their staff is enlarged. This projected level of abuse amounts to more than 5 percent of Medi-Cal payments to pharmacies, a level which should point not only to need for more rigorous enforcement, but to need for program revision. Medi-Cal ceiling price controls are viewed by many pharmacists as complex, arbitrary, and unfair, and contribute to retaliation in the form of overbilling. In addition, the "customary and usual" limitation upon providers' prices is largely unenforceable, as is the requirement that pharmacists dispense the lowest cost drug in stock that meets the medical needs of the beneficiary.

# <u>Problems in Determination of the Dispensing Fee</u>

The total payment to pharmacy vendors for prescription drugs dispensed to Medi-Cal beneficiaries equals ingredient cost plus a flat dispensing fee per prescription. On March 7, 1977, the fee was increased from \$2.86 to \$3.06, the increase having been justified as a full offset

<sup>2/</sup>Drug Utilization Review Unit, Budget Change Proposal, June 8, 1977, draft copy.

to the savings to Medi-Cal (and reduction in revenue to pharmacies) estimated by DOH to arise from the EAC programs. A study by a contractor to DOH designed to establish the proper level of the fee was completed in September, 1977, but DOH's recommendations had not been made by date of termination of this study.

### Finding:

The dispensing fee portion of Medi-Cal's payment for drugs cannot be measured accurately.

- The 1977 fee study found a range of dispensing charges from about \$1.00 1. prescription to more than \$5.00. Few low-cost chain pharmacies partici No reasonable means exists for selecting a fee from that range. Even if dispensing costs per prescription could be determined for each pharmacy, a judgment must be made as to which cost in the distribution among pharmacies ought to be settled upon as the fee level. It would be reasonable to establish the fee at a cost representing a standard level of efficiency in store management. But because of substantial differences among stores in quantity per prescription and mix of drugs, cost per prescription is not a reasonable basis for comparison among pharmacies. Even if it were it is difficult to provide justification fo selection of average cost or price or a given percentile from the range of costs found to exist. The fact that the range is extremely wide exacerbates this problem. In addition, the absence of chain store data from past fee calculations has greatly impaired their validity.
- 2. Because Medi-Cal's payment for ingredients exceeds average price paid by pharmacies, the fee ought to be reduced by the amount of that excess whatever it may be. It was explained above that AWP, upon

which most Medi-Cal ceilings are based, exceeds the actual price paid by pharmacies for ingredients by an amount that averages perhaps 15 to 18 percent but varies widely among pharmacies. If the fee were defined as the per prescription costs of a pharmacy other than ingredient costs as currently defined, the sum of the two would be excessive by the amount by which AWP exceeds actual ingredient prices paid by pharmacies. Department of Health staff accommodate this problem by recognizing in principle that the fee ought to fall short of full dispensing cost.

3. The range of possible cost imputations and methods of cost allocation is very large. The decision in a cost study to impute certain costs by, for example, standardizing pharmacists' salaries, and to allocate storewide costs to pharmacy on a sales basis, floor space basis or some other basis are decisions made independent of the objective cost data.

# Alternative Price Control Policies

There are serious deficiencies in Medi-Cal's current ceiling price control program. Some of the alternatives considered here are or were recently actively under consideration by DOH. Some are moderate extensions of existing policy. Others, such as government ownership of Medi-Cal pharmacies, entail major changes in the role of government. Some are treated in detail in this chapter and related appendices. Others receive cursory treatment because there is little experience upon which to draw.

#### Finding:

Most alternative means of price control offer only incomplete or auxiliary solutions to Medi-Cal price control problems.

1. Expansion of existing ceiling controls by adding drugs to the MAIC list, provides potential savings of \$1.27 million, but does not overcome the inherent shortcomings of ceiling price controls. The Maximum Allowable Ingredient Cost (MAIC) program is the list of price maxima for about 100 multi-source drugs. At the time this study was undertaken, DOH was preparing to add more drugs to the list. Such action was probably feasible and entailed no significant program changes.

In order to obtain an estimate of savings likely to be achieved by DOH the California Pharmaceutical Association (CPhA) at the request of the Department of Finance study group suggested additions to the MAIC. The Department of Finance study group established that the savings arising from these recommendations would total about \$1.27 million (Appendix 7).

This program expansion cannot eliminate the defects inherent in ceiling price controls, the chief effect of which is to limit savings. Arbitrary reduction in MAIC ceilings is prevented by Medi-Cal regulations which were promulgated following a lawsuit in 1973.

<sup>3/</sup>Pharmaceutical Manufacturers Association, et. al. vs. Brian, Superior Court of California, Sacramento, No. 221773.

- 2. As the market becomes better understood state government ownership of pharmacies might be considered for underserved areas. Precedent exists for government ownership of Medi-Cal providers, in the form of county hospitals, most of which dispense large quantities of drugs and serve a unique clientele. But consideration of government ownership of all or most pharmacies would introduce an option with implications lying well beyond the study's scope. Greater familiarity with the market is necessary before costs and benefits of this option could be measured.
- 3. Mail-order pharmacies, as an ancillary system, might meet needs of the rural population, and for maintenance drugs. From a number of locations in the United States, including two in California, the Veterans Administration fills about 16 million prescriptions per year by mail. About six nongovernmental firms provide mail-order drug service. The largest of these, the National Retired Teachers' Association/American Association of Retired Persons Pharmacies dispenses about four million prescriptions from seven locations. All firms in the business have ties with an employee or other group, and serve primarily the elderly and others with chronic illnesses who continually use large quantities of the same medication, and persons in rural areas whose access to retail pharmacies is limited. The dispensing cost per prescription is

<sup>4/&</sup>quot;Mail-order Rx Field Girds for New Growth," American Druggist, November 1976, p. 58.

- relatively low in mail-order firms, but may not be lower than urban chains. Mail-order firms probably cannot effectively serve the many patients who require immediate service. For that reason this study does not pursue this option, but DOH ought not to eliminate consideration of it for a portion of Medi-Cal's needs, as they become more familiar with prices in the retail pharmacy market.
- 4. Savings and feasibility of the Modified Volume Purchase Plan will remain highly speculative until tested. The California State Legislature recently opposed this plan. Beginning in 1975, DOH began to devote time to consideration of ways in which it might be able to take advantage of the fact that other Federal, state, and county agencies were buying drugs at prices one-third to one-half of those paid by Medi-Cal. It designed the Volume Purchase Plan (VPP) which proposed that the State buy drugs on a bid basis, that the State assume ownership of the drugs, but that they be shipped directly to wholesalers and then to retailers, both of whom would receive a fee for their services. Voluntary participation of manufacturers, wholesalers, and pharmacies was necessary to the program's success.

Cooperation was not forthcoming, even on a pilot basis. In March, 1977, DOH abandoned that plan, and announced in its stead the Modified Volume Purchase Plan. It is a rebate plan. Manufacturers were to be invited to offer the State a refund on drugs they sell to Medi-Cal through existing channels. A single successful bidder would be selected for each multi-source drug. Pharmacies were to be offered \$0.30 per prescription to induce them to dispense the brand selected. Opposition by the pharmaceutical manufacturer's industry and by the Legislature caused DOH, in September 1977, not to go forward with a pilot project to test the concept.

In Appendix 8, the Modified VPP is analyzed. Savings are possible but their attainment rests primarily upon the average level of manufacturers' rebates offered. The purpose of a pilot project is primarily to estimate that magnitude. The Modified VPP is compatible with this study's primary recommendation.

- 5. Expansion of the principle of drug substitution. Medi-Cal requires that pharmacists dispense the lowest-cost multi-source drug in stock. In addition to this largely unenforceable regulation, Medi-Cal forces substitution via the MAIC program. Drug substitution is viewed in Appendix 1 as an element with substantial potential for price reduction, but has been largely beyond the scope of Medi-Cal policy. As purchaser of almost 20 percent of the prescription drugs sold in California, DOH could encourage generic prescribing and drug price advertising, take price into consideration in making formulary changes, and promote changes in state law which encourage pharmacies to substitute. The primary recommendation of this report is compatible with drug substitution.
- 6. Purchase on the basis of competitive prices. This alternative is the major focus of this study because it offers a workable policy utilizing existing providers and distribution channels, and because analysis of the option provides market information that is valuable, whichever alternative is adopted. Observation of prices in chain drug stores suggested that large savings could be had by limiting Medi-Cal's purchases to stores with comparable prices. In Chapter IV the results of a retail pharmacy price survey are reported, and in Chapter V a policy is outlined, centering on purchase on the basis of competitive prices.

#### CHAPTER IV

## COMPARISON OF MEDI-CAL PAYMENTS TO MARKET PRICES

Analysis of market prices makes it possible to determine whether the State could save money if it were to buy at prices the general public, or some of them, pays for drugs. The range of prices among pharmacies in California was believed to be large. The purpose of undertaking a survey of prices was primarily to compare them with prices paid by Medi-Cal.

The price survey undertaken by the Department of Finance study team consisted of recording and analyzing the prices of 16 drugs, in 530 stores located in Los Angeles, Alameda, Sacramento, and San Diego counties. Those counties accounted for 53.8 percent of Medi-Cal drug claims in the period July-December, 1976. Price data was obtained directly from price posters in each pharmacy during the month of May, 1977. The 530 stores sampled were selected from all pharmacies in the four counties except hospital pharmacies. A discussion of survey methodology appears in Appendix 9.

The 16 drugs included in the study produced a total of 27 prices (either one or two quantities per drug). The device that is used to summarize store-by-store price differences is the "market-basket," which is the sum of the 27 drug/quantity prices for each store.

Since the primary purpose of the market study was to focus upon the differences in price levels among stores, not upon differences in prices for individual drugs, the drug sample met a variety of criteria designed to ensure that the 27 drug/quantity sample would produce prices representative of the price levels of the stores from which they were obtained (see Appendix 9). The store sample used produced a 95 percent level of confidence that the estimate of the average market-basket price for the four-county area was within 1.5 percent of the actual mean.

In drawing conclusions about statewide price differences the samp data is weighted to reflect the number of pharmacies in each county. For purposes of market price comparisons reported below drug volume weights were not applied because the pattern of drug usage of the general public is not known. But for the purpose of savings calculations in the latter part of this chapter, prices are weighted by Medi-Cal volume.

# Analysis of Price Differences

4

Price deciles have been chosen as the most useful means for comparing prices among stores. In Chapter V savings are calculated in terms of the amounts Medi-Cal can save by buying at each market price decile.

Finding: There exist wide variations in pharmacies' drug prices to the general public.

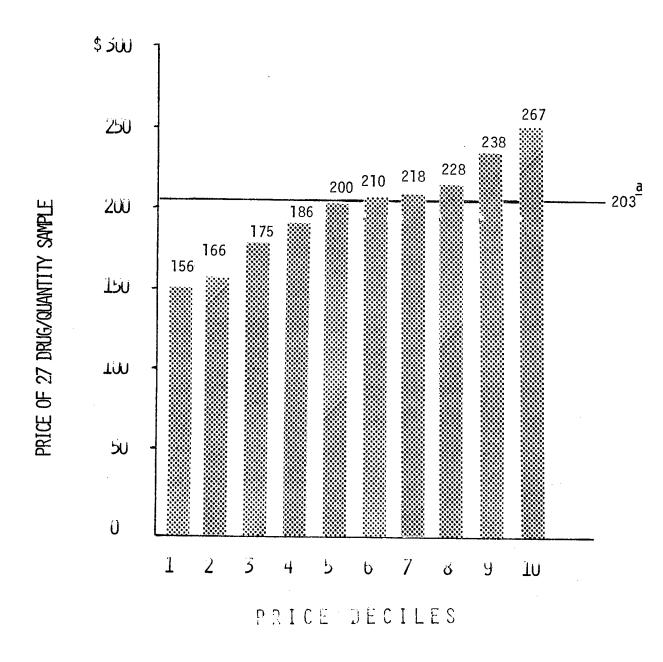
1. <u>Drugs in the highest price decile cost 71 percent more than those</u>
<u>in the lowest decile of pharmacies</u>. The total of all 27 prices in
the surveyed drug/quantity combination produces the "market basket"

price used to measure price differences among pharmacies. Figure 4-1 shows that the lowest-price 10 percent of stores (the lowest-price decile) charges the general public \$156 for that market basket, and the highest price \$267 on the average, or 71 percent more. In approximately 50 percent of the stores in our four-county sample, the sum of posted prices is less than the \$203 Medi-Cal price ceiling for the same drugs.

While Figure 4-1 shows the range of prices paid by the general public in California, Figure 4-2 shows the prices paid by Medi-Cal, which range from an average of \$156 for the lowest-price decile to \$201 for the highest-price. This Medi-Cal market basket for each store was computed by summing the ceiling prices or the actual posted prices, whichever was less, for each drug. This mode of calculation reflects the requirement that pharmacies bill Medi-Cal the maximum allowable price or their "customary and usual" charge, whichever is less.

Medi-Cal and the general public pay the highest prices in large Medi-Cal stores and the lowest in large chain stores. Large chain stores (five or more stores) tend to have the lowest prices and large Medi-Cal pharmacies (in excess of \$100,000 sales to Medi-Cal per year) have, as a group, the highest prices. Figure 4-3 shows this relationship, with the average large chain store charging the general public \$175 for the same drugs that cost an average of \$218 at community and professional pharmacies and \$244 at large Medi-Cal pharmacies. The pattern of prices paid by Medi-Cal is in each case similar, but is of course lower because of the effect of price ceilings, explained above.

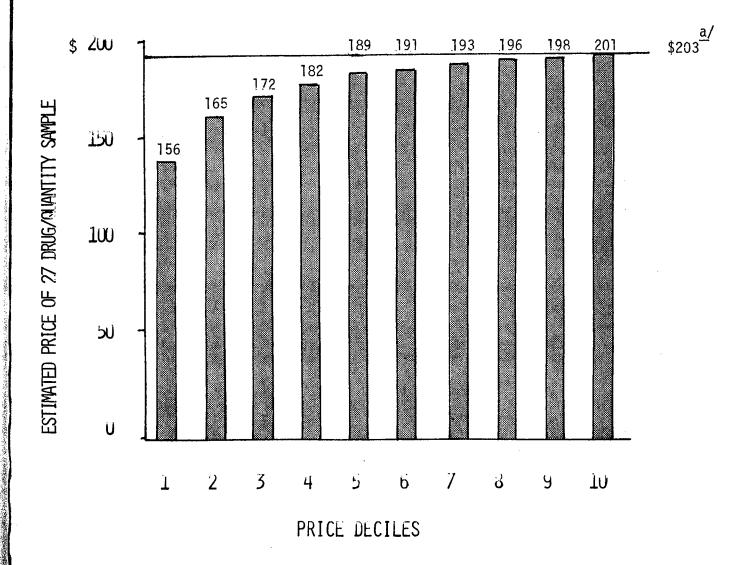
POSTED PRICES OF PRESCRIPTION DRUG SAMPLE BY PRICE DECILES



SOURCE: DOF Drug Survey Data, May 1977.

 $\underline{a}/\text{Maximum}$  price paid by Medi-Cal for 27 drug/quantity sample

FIGURE 4-2
ESTIMATED PRICE TO MEDI-CAL FOR PRESCRIPTION DRUG SAMPLE BY PRICE DECILE

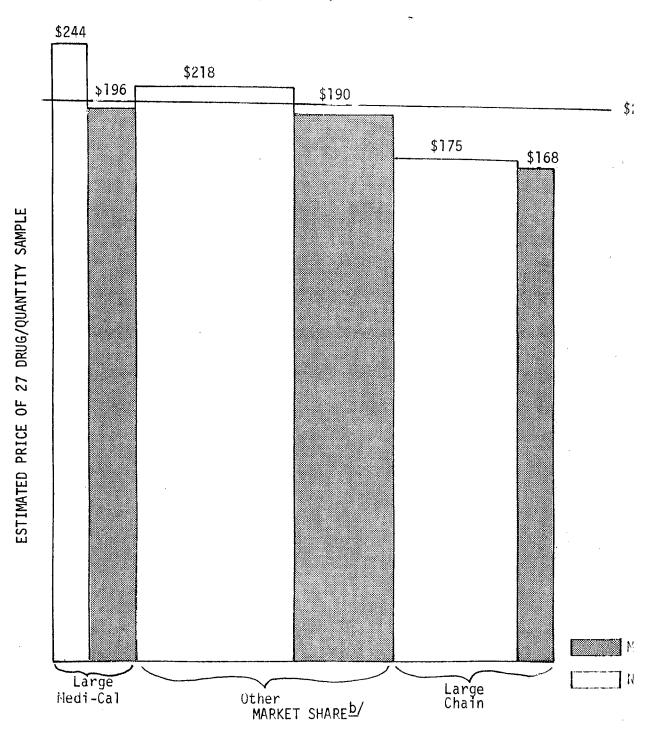


SOURCE: DOF Drug Survey Data, May 1977 and Medi-Cal Intermediary Operations.

 $<sup>\</sup>underline{a}$ /Maximum price paid by Medi-Cal for 27 drug/quantity sample.

FIGURE 4-3

ESTIMATED PRICES OF DRUG SAMPLE TO MEDI-CAL AND TO NON-MEDI-CAL CONSUMERS, BY PROVIDER TYPE



SOURCE: Chapter I, and DOF Drug Survey Data, May, 1977.

a/Maximum price paid by Medi-Cal for 27 drug/quantity sample.  $\underline{b}$ /Column width represents approximate relative annual sales per Tables 1-3 and 1-4, exclusive of hospital pharmacies.

- 3. Prices of large Medi-Cal stores are usually set at Medi-Cal price ceilings. Figure 4-3 tends to confirm the observation made in Chapter III that large Medi-Cal stores use Medi-Cal ceilings as, in effect, their price list. The most any store can charge Medi-Cal for the market basket is \$203. Large Medi-Cal stores charge an average of \$196. Few of the posted prices of large Medi-Cal stores fall below Medi-Cal maxima. Thus the effect of Medi-Cal ceilings is to raise prices in some stores, or at least to prevent competition from depressing them. At the other extreme, few prices of large chains are as high as the Medi-Cal maxima.
- 4. Chain store prices are lower than prices of other types of stores

  in each sample county. Table 4-1 shows that average prices of large
  chain stores are not only low in the four-county sample area, but
  are consistently low in each county, reflecting in part the statewide pricing policies of some of the very large chains.
- 5. Price differences among market areas should be considered in establishing price control policies. Table 4-1 shows that the average price to Medi-Cal for the market basket in Los Angeles County is about 8 percent higher than in San Diego County. Differences among smaller market areas are probably even greater. This suggests that the state treat market areas differently in order to minimize its costs in each area.

TABLE 4-1

ESTIMATED PRICE TO MEDI-CAL
OF 27 DRUG/QUANTITY SAMPLE
BY COUNTY AND BY PROVIDER TYPE

	Large <u>Medi-Cal</u>	Large <u>Chain</u>	<u>Others</u>	County <u>Average</u>
A1 ameda	\$194.31	\$168.63	\$193.63	\$190 <b>.3</b> 4
Los Angeles	201.50	172.63	192.04	193.03
Sacramento	191.87	152.25	192.57	186.53
San Diego	192.86	154.21	174.02	178.63
Statewide	196.35	168.32	190.25	189.55

SOURCE: DOF Drug Survey Data, May, 1977.

NOTE: County and statewide averages are weighted by number of stores in each county.

6. Chain stores are the least expensive for each drug. In Table 4-2 the average price charged by each of the three categories of pharmacies is calculated as a percentage of the average price statewide for each drug/quantity. These relative price levels or indices are arrayed in ascending order of drug price in Figure 4-4. The average chain store price is below the price of the other two categories of stores for every drug. This systematic difference in costs to the State by type of store suggests that price controls ought to focus on store-by-store differences, as well as differences among drugs.

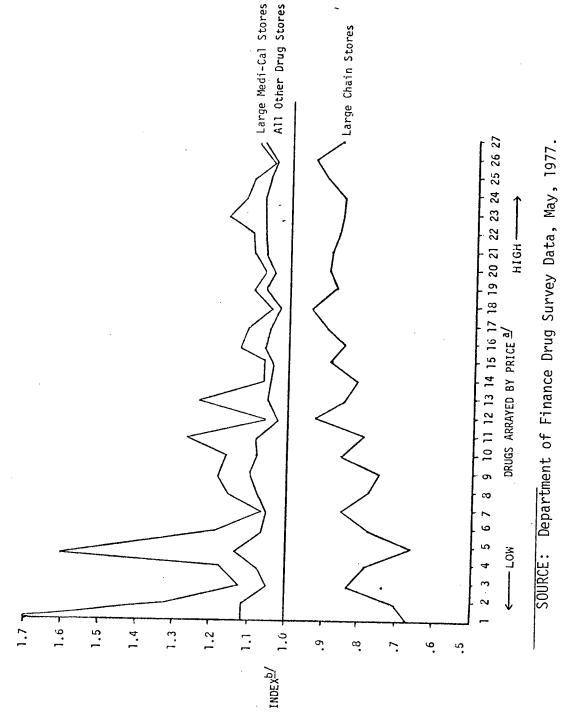
TABLE 4-2 AVERAGE POSTED PRICE AND INDEXED PRICE OF 27 DRUG/QUANTITY SAMPLE BY PROVIDER TYPE

	C+0	1.07 1.08 1.05 1.05 1.06 1.05 1.05 1.05 1.05 1.05 1.05
Index by Store Type	8+0	1.10 1.10 1.10 1.10 1.10 1.10 1.10 1.10
Inde	A+0	0.83 0.88 0.88 0.88 0.88 0.88 0.93 0.70 0.75 0.75 0.78 0.78 0.78 0.78 0.78 0.78 0.78 0.78
	Rank in Fig. 4-4 <u>a/</u>	22 111 27 115 115 115 115 116 117 118 118 118 118 118 118 118 118 118
o) l	D All Types	\$ 11.33 7.73 9.50 16.48 2.72 3.32 4.84 7.80 8.30 14.14 7.69 13.05 14.65 10.04 3.29 4.34 5.50 2.95 3.47 4.69 3.30 4.34 6.98 11.82 11.82 11.82 11.82
Average Price by Store Type	C Other	\$ 12.07 8.28 9.94 17.54 3.73 3.73 3.73 3.73 14.84 8.14 8.13 15.06 10.41 3.47 4.56 5.60 3.26 3.74 4.56 5.12 3.74 4.56 5.12 3.74 4.56 5.12 3.74 4.56 5.12 3.74 4.56 5.12 3.74 4.56 5.12 3.74 5.11 5.11 5.11 5.11 5.11 6.14 6.14 6.15 6.16
rage Price	B Large Medi-Cal	\$ 12.42 6.11 8.31 10.57 18.28 4.63 9.22 15.56 8.66 14.70 9.04 15.41 10.81 3.69 4.59 5.90 3.91 4.98 8.59 14.21 11.87
Ave	Large Chain Stores	\$ 9.35 6.27 6.33 13.75 13.75 12.39 6.83 7.39 10.71 8.02 13.56 9.00 2.72 3.68 5.09 5.91 9.58
1	<u>Drug Name</u>	Aldomet Tablet 250MG/100 Ampicillin Tablet/Capsule 250MG/20 Ampicillin Tablet/Capsule 250MG/40 Diabinese Tablet 250MG/50 Diabinese Tablet 250MG/100 Digoxin Tablet 0.25MG/100 Erythromycin Stearate Tablet 250MG/40 Indocin Capsule 25MG/50 Indocin Capsule 25MG/50 Lasix Tablet 40MG/100 Mellaril Tablet 25MG/100 Mellaril Tablet 25MG/100 Penicillin G Tablet 40MG/40 Penicillin G Tablet 40MG/40 Penicillin G Tablet 40MG/40 Percodan Tablet 3MG/100 Prednisone Tablet 5MG/100 Prednisone Tablet 5MG/50 Prednisone Tablet 5MG/100 Ietracycline Tablet 5MG/50 Valium Tablet 5MG/50 Valium Tablet 5MG/50 Valium Tablet 5MG/50 Valium Tablet 5MG/100 Zyloprim Tablet 5MG/100 Zyloprim Tablet 5MG/100

SOURCE: DOF Drug Price Survey, May 1977

a/Ranked in ascending order of average price

FIGURE 4-4
INDEXED DRUG PRICES FOR THE 27 DRUG/QUANTITY
SAMPLE BY PROVIDER TYPE A/



7. The fee plus ingredient cost mode of Medi-Cal payment distorts prices of large Medi-Cal stores. Figure 4-4 shows the greatest price spread among inexpensive drugs. This is an artifact of the ingredient cost plus dispensing fee mode of Medi-Cal payment. Drug number 2, for example, is 30 mg. phenobarbital tablets in quantities of 100. The statewide average price for this drug is \$2.95. The large chain store average is \$2.07 (0.70 of the statewide average) while that of large Medi-Cal providers is \$3.91 (1.33 of the statewide average). We noted above that large Medi-Cal stores price at or above the Medi-Cal ceiling. The dispensing fee at the time of the survey was \$3.06 and the ingredient maximum \$0.64, totalling \$3.70. Thus the high ratio of fee to ingredient cost for low-priced drugs produces a high total price in large Medi-Cal stores, compared to large chains who do not consider Medi-Cal maxima in setting prices.

# Estimate of Potential Savings

If Medi-Cal buys drugs at an average price equal to the average market price of the lowest price 40 percent of pharmacies, it can save 8.0 percent. If it buys at an average price equal to the average market price of the lowest price 20 percent of pharmacies, it can save 16.6 percent. In the balance of this chapter calculations are provided to support the foregoing statements. Translation of these percentage savings into dollar savings is accomplished in Chapter V.

In Figure 4-1, the range of prices charged the general public for drugs was presented in terms of price deciles. That data reflects the prices charged by all stores in the four-county sample, because prices

obtained from sample stores are weighted by the proportion of all stores in each county to the total number of stores in the four counties. It reflects, of course, not only the prices for the market basket of drugs sampled, but the relative prices of all prescription drugs on the Medi-Cal formulary (see Appendix 9 for an explanation of selection of drugs). The prices that appear in Figure 4-1 are not weighted to reflect the volume of each sampled drug used by the general public since those magnitudes are not known.

In order to estimate the savings that Medi-Cal might achieve by buying at various decile levels, each drug comprising the decile data in Table 4-1 is weighted by the proportion of Medi-Cal purchases of the mark basket drugs in 1975-76. These weighted prices are used to estimate potential Medi-Cal savings in two ways.

Calculation using only market price data from sample pharmacies. the first column of Table 4-3 price deciles weighted by Medi-Cal volu are displayed cumulatively, i.e., the first decile is the weighted average price for the lowest price 10 percent of stores in each count the second decile is the weighted average price for the lowest price 20 percent of stores, etc. The calculated weighted average price pai by Medi-Cal for the market basket is \$193.74. Each store's price is obtained by summing for all drugs in the sample the ceiling prices or the actual posted prices whichever is less. To this price are applie the weights reflecting number of stores in the county and Medi-Cal usage. The difference between \$193.74 and the cumulative weighted average price of the drug sample is shown in Column 2 for each decile and is shown in percentage terms in Column 3. Thus, for example, Medi-Cal's potential saving if it were to buy at prices available from the lowest price 20 percent of stores in each county would be 16.8 pe cent, and from the lowest price 40 percent would be 10.9 percent.

TABLE 4-3 ESTIMATE OF POTENTIAL SAVINGS, BASED ON POSTED PRICES FOR 27 DRUG/QUANTITY SAMPLE, BY CUMULATIVE PRICE DECILE

	(1)	(2)	(3)
Cumulative Price Decile	Cumulative Estimated Weighted Average Price of Drug Sample	Estimated Average Cost to Medi-Cal (\$193.74) Less Amount in Col. (1)	Estimate of Potential Savings Percent
1	\$156.09	\$37.65	19.4%
2	161.14	32.60	16.8
3	166.35	27.39	14.1
4	172.68	21.06	10.9
5	179.60	14.68	7.6
6	185.82	7.92	4.1
7	192.00	1.74	0.9
8	196.80	(3.06)	(1.1)
9	202.38	(8.64)	(4.5)
10	212.07	(18.33)	(9.5)

SOURCE: See explanation in text.

Calculation by comparison of actual Medi-Cal payments to market price 2. data obtained from sample pharmacies. An alternative means of estimating potential savings makes use of Medi-Cal's paid claims records for drugs dispensed in May, 1977, the same month in which market price data was obtained. In June, 1977, Medi-Cal actually paid pharmacists \$554,645 for the 27 drug/quantity items dispensed

in May, 1977. Column 1 in Table 4-4 is the product of the prices

Medi-Cal would have paid if it purchased at market price, and the actual
number of prescriptions dispensed, presented cumulatively by price
deciles. Column 2 records the dollars that Medi-Cal would have saved
if it had paid those prices. The percentage savings appear in Column 3.

Thus, for example, Medi-Cal's potential savings if it were to buy at
prices available from the lowest price 20 percent of stores would be 16.0
percent, and from the lowest price 40 percent would be 8.0 percent.

TABLE 4-4

ESTIMATE OF POTENTIAL SAVINGS,

BASED ON POSTED PRICES FOR DRUG/QUANTITY SAMPLE
AND PAID CLAIMS FOR MAY, 1977, MONTH OF SERVICE
JUNE, 1977, MONTH OF PAYMENT, BY CUMULATIVE PRICE DECILE

1       \$432,863       \$121,782       22.0%         2       462,536       92,109       16.6         3       488,319       66,326       12.0         4       510,054       44,591       8.0         5       530,513       24,132       4.4	mulative Price Decile	Medi-Cal if Posted	(2) Cost to Medi-Cal (\$554,645) Less Amount in Col. 1	(3) Estimate ( Potential Sa Percent
3 488,319 66,326 12.0 4 510,054 44,591 8.0	7	\$432,863	\$121,782	22.0%
4 510,054 44,591 8.0	2	462,536	92,109	16.6
500 510	3	488,319	66,326	12.0
5 530.513 24.132 4.4	4	510,054	44,591	8.0
24,132 4.4	5	530,513	24,132	4.4
6 549,101 5,544 1.0	6	549,101	5,544	1.0
7 569,274 (14,629) (2.6)	7	569,274	(14,629)	(2.6)
8 583,676 (29,031) (5.2)	8	583,676	(29,031)	(5.2)
9 601,867 (47,222) (8.5)	9	601,867	(47,222)	(8.5)
10 623,127 (68,482) (12.3)	10	623,127	(68,482)	(12.3)

SOURCE: Data Processing Service Branch, DOH and DOF Drug Price Survey, May 1977. See explanation in text.

The second of these two methods has the advantage that it compares posted prices with actual Medi-Cal payments. It has the disadvantage that the comparison is made at only one point in time (May, 1977) and that the quantities of each drug used for comparison do not reflect usage of that drug in all quantities.

The first of these methods corrects for the latter problem, but assumes that pharmacies comply with the requirement that Medi-Cal be charged the lesser of their customary and usual price and the Medi-Cal ceiling. This is often not the case and may account for the lower savings reflected in the second method.

For purposes of estimating dollar savings in Chapter V the lesser of the two savings estimates is used.

#### CHAPTER V

## A MARKET PRICE PROGRAM

The drug price survey whose results are reported in Chapter IV found that prices of prescription drugs differ greatly among California's pharmacies. In order to obtain substantial savings it is necessary that the State make its purchases at prices in the lower half of the range of available prices.

#### Finding:

If Medi-Cal buys drugs at an average price equal to the average market price:

- a. of the lowest price 40 percent of pharmacies, it can save \$9.5 million.
- of the lowest-price 20 percent of pharmacies, it can save \$19.7 million.

#### Recommendation:

The Department of Health should develop a method, to submit with the 1979-80 budget request, to buy prescription drugs for the Medi-Cal program at prices at which lower-price pharmacies sell to the general public.

The savings that can be achieved by a plan in which the State pays an average price equal to the average market price of the lowest-price 40 percent of pharmacies is estimated to amount to \$9.5 million, based upon 1976 Medi-Cal volume. If Medi-Cal purchases were restricted to the

lowest-price 20 percent \$19.7 million could be saved (Table 5-1). This estimate reflects price reductions of 3.0 and 16.6 percent, respectively, applied to 1976 drug volume exclusive of certain drugs and market areas. It was estimated that savings attainable by extension of the existing MAIC program will be limited to \$1.25 million (Chapter III), although additional savings could be achieved in the unlikely event that DOH decides to roll back the recent \$.20 fee increase, or if additional MAC ceilings are announced.

TABLE 5-1
ESTIMATED SAVINGS OF MARKET PRICE PROGRAM,
BASED ON 1976 DATA

		<u>M11110n \$</u>
and	0.6 million total Rx drug sales less 15 percent drugs area not covered (see Sections 2 and 4 in this oter for exclusions).	\$118.7
Two	savings estimates are presented:	.i
1.	8.0 percent savings if Medi-Cal buys at an average price equal to the average price of the lowest-price 40 percent of pharmacies.	\$ 9.5 
2.	16.6 percent saving if Medi-Cal buys at an average price equal to the average price of the lowest-price 20 percent of pharmacies.	\$ 19.7

SOURCE: Tables 1-3 and 4-6.

The details of a program that takes advantage of these market price differentials are compared in Table 5-2 with the characteristics of the existing ceiling price programs. Any price control program should take cognizance of the differences among geographic areas and kinds of providers. Services provided and the drugs to be covered by the program must be identified. The mode of determining prices must be spelled out as well as the role of the ancillary modes of control identified in Chapter II

#### TABLE 5-2

#### COMPARISON OF FEATURES OF CEILING PRICE AND MARKET PRICE PROGRAMS

	Present (Ceiling Prices)	Proposed (Market Prices)
Saving	\$1.25 million	\$9.5 - 19.7 million
Price determination	<ol> <li>Published ceiling prices, plus fee</li> <li>Periodic update</li> <li>Fiscal intermediary</li> </ol>	1. Competitive basis 2. Update based on index 3. MAIC, EAC eliminated 4. MAC retained 5. Fee-ingredient cost distinction eliminated 6. Fiscal intermediary
Drugs covered	All	All, but only 300, or 86 percent, on bid basis
Number of Pharmacies Participating	<ol> <li>All pharmacies         eligible</li> <li>Almost all participate,         but chains under-         represented</li> <li>Concentration in a         few stores</li> </ol>	<ol> <li>All pharmacies eligible</li> <li>Law may permit reduced participation</li> </ol>
Geographic area	Price ceilings same statewide	<ol> <li>Divide state into market areas based upon price differences.</li> <li>Rural and ghetto areas present problems</li> <li>Pilot program desirable</li> </ol>
Compliance	Complies with Federal and state law	<ol> <li>"Freedom of choice" needs clarification.</li> <li>Not in conflict with Federal MAC-EAC regulations</li> </ol>
Hospital pharmacies	Subject to ceiling controls, except flat rate for L.A. County	Permit to buy in at pre- determined price
Services	<ol> <li>Medi-Cal regulations do not specify services.</li> <li>Services provided differ among pharmacies</li> </ol>	<ol> <li>Deliver if medically necessary, and provide separate charge.</li> <li>Consider community-wide patient profiles and emergency services.</li> <li>Identify required services for price purposes.</li> </ol>
Nursing homes	Ceiling price controls do not distinguish	<ol> <li>Consider separate prices for nursing home drugs</li> <li>Consider direct payment to nursing homes.</li> </ol>
Other price contr <b>o</b> ls	Modified VPP considered	Integrate other approaches: Consider VPP, mail order, government ownership, drug substitution
Administration	Limited market data	Based upon market information

The purpose of the discussion that follows is to explain in a general way how these matters might be dealt with within the context of a market price program. A framework is provided, not a fully operable plan of action.

- 1. Price determination. The proposed program could entail periodic (probably annual) competitive bids among pharmacies, in selected quantities per drug. Update between bid dates could be based upon a price index. (Prices are now updated quarterly). An alternative in certain situations may be a "buy-in" in which DOH invites pharmacy participation at price levels which are competitively determined. All ceiling prices would be eliminated except those mandated by the Federal MAC program. The distinction between fee and ingredient cost would cease to exist (except see 2 below). The fiscal intermediary would continue to process claims submitted by pharmacies with whom DOH had contracted.
- 2. <u>Drugs covered</u>. It is suggested that the market price program be limited to the largest volume 300 drugs which together comprise 86 percent of Medi-Cal drug payments. It is not feasible for pharmacies to bid on all of the more than 2,000 drugs used annually. The other 14 percent of drugs could be controlled at the present AWP plus fee level, and it is possible that close observation of their price behavior will suggest other simpler means to handle them.
- 3. <u>Number of pharmacies participating</u>. Selection by competitive bid of pharmacies entitled to serve Medi-Cal raises the possibility that beneficiaries' access to pharmacies will be materially reduced. The following comments are pertinent:

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- a. All pharmacies in the State are legally entitled to serve
  Medi-Cal beneficiaries and all would continue to be eligible
  to compete for Medi-Cal business under the proposed market price
  system. Both systems impose price constraints as a condition
  of participation.
- b. Certain large chain stores have indicated that they would bid upon Medi-Cal business. The percentage of business Medi-Cal now does with large chains is substantially lower than the percentage of purchases at chains made by the more priceconscious general public.
- c. A pronounced trend to chain drug stores exists, paralleling the long completed trend to food chains. The number of community pharmacies is declining. Problems of beneficiary access must be viewed in that context.
- d. A recent interpretation of the "freedom of choice" provision of Title XIX of the Social Security Law appears to find acceptable limitation in number of Medicaid providers for cost reasons.

# 4. <u>Geographic</u> area.

The following considerations bear upon geographic differences among pharmacies.

a. Data developed in the market price study discloses substantial differences in prices among counties. The savings estimated for the market price program take county differences into account by

<sup>1/</sup>Letter Regional Attorney, Department of Health, Education and Welfare, Region VIII, to Acting Regional Commissioner, SRS, November 4, 1976.

including 10 percent of each county in each decile. It is probably necessary to pay higher prices in some areas than in others in order to achieve both maximum savings and adequate access in all areas.

Rural and ghetto areas provide unique problems. Calculation of savings attributable to the market price program excludes the Medi-Cal drug volume in 22 rural counties until better understanding of beneficiary location and buying habits is achieved. Those 22 counties do only 2 percent of Medi-Cal volume.

Preliminary analysis of a 16-square mile portion of East Los Angeles reveals a large percentage of large Medi-Cal stores, and no chains. This and other such areas may fail to yield competitive market prices, and other means of price control may have to be used.

- c. The program issues raised in this chapter can probably best be studied in a limited geographic area. A pilot study in perhaps two large counties may be desirable.
- 5. <u>Services</u>. Medi-Cal regulations do not specify the services to be provided by pharmacies.
  - a. Delivery is offered by some stores, but not others. Chain store almost invariably do not deliver. Of those who deliver, some charge for the service. Some do not deliver to all locations, a all hours, and at frequent intervals. For price purposes, a reasonable solution is to specify delivery charges separate from the drug price, and to allow delivery only if medically necessary

- b. Emergency prescriptions are those provided at other than normal store hours. The extent of the practice is unknown, but hospital pharmacies frequently provide emergency service. Solution of the problem on a regional or market area basis may be preferable to requiring every pharmacy to provide emergency service. Few pharmacies provide that service now.
- c. Some pharmacies maintain for each patient a personal medication record, or patient profile, whose primary purpose is to record drug interactions, and patient reactions to drugs. There are those who believe that the cost of maintaining such records, and the time needed to search them in order to advise the patient and physician is too high, and that their purpose is defeated by patients who shop at more than one pharmacy. If Medi-Cal finds that this service is essential, it might best be provided by a central computer system. The data now provided by MIO for peer review purposes is comparable.

The services discussed above are those most readily identified and perhaps most costly, but there is a broad range of services which could be required as a condition of participation in the Medi-Cal program, whatever the device used to control Medi-Cal prices.

6. <u>Compliance</u>. A market price program appears not to conflict with the "freedom of choice" provision of Title XIX of the Federal Social Security Law, but clarification would be needed. There also appears to be no conflict with the wording of the MAC-EAC regulations in Section 250.30 of CFR No. 45.

- 7. Hospital pharmacies. Eight percent of Medi-Cal's drug purchases are made from hospital pharmacies. Ten of the 71 largest drug providers are county hospitals. Success of the market price program is based upon the premise that low prices will be achieved as a result of competitive pressures. Hospitals do not compete in price terms. In general, hospital pharmacies charge at a high percentage markup, and are one of the most profitable departments in the hospital. Because hospitals are important pharmacy providers and not price competitive, they should probably be permitted to buy into the Medi-Cal program at a level determined by other competitors. Medi-Cal's largest provider, the Los Angeles County-USC Medical Center, is exempt from existing controls under the Los Angeles County waiver.
- 8. Nursing homes. Thirteen percent of Medi-Cal's purchases of prescription drugs from pharmacy vendors are delivered to nursing home patients.

  Nine of Medi-Cal's 71 largest providers serve nursing homes exclusively.

  Many other pharmacies deliver drugs to one or a few nursing homes in addition to their walk-in business. The current ceiling price control program does not distinguish nursing home patients from other beneficiaries. The economics of provision of such services is much different from walk-in business, however, and the opportunity for improper deals between pharmacies and nursing homes exist. A market price program ought, once established, to consider establishing separate prices for the two classes of business. Alternatively, drug payments could be made directly to nursing homes.
- 9. Other price controls. The Modified Volume Purchase Plan was, until recently, under consideration, not to replace ceiling prices, but as an adjunct to them. In the same way a market price program ought not to

- Case 1:01-cv-12257-PBS Document 6702-16 Filed 11/25/09 Page 36 of 37 be viewed as a universal solution to achievement of maximum effectiveness in drug price control. It is compatible with the Modified Volume Purchase Plan as long as use of VPP drugs by pharmacies is achieved by means of incentives. The State is best served by removing decisions on drug selection from the State to pharmacies. Mail order pharmacies ought to be considered as a possible solution for certain drugs, and possibly for rural areas. Private pharmacies might be induced to enter the mail order field—it is being done in other states. Government—owned pharmacies can play a role. County hospitals are major providers now. If private pharmacies cannot adequately serve ghettos, hospitals and clinics might meet the need. Drug substitution ought to be actively promoted, whatever the system of price control.
- 10. Administration. DOH's knowledge of the market it seeks to control is fragmentary. A market price control program cannot be operated without systematic collection and analysis of market data.

# APPENDIX 1 DRUG SUBSTITUTION

One means of enforcing use of less expensive drugs in California is a recent law permitting drug substitution. Medi-Cal regulations have long required that the pharmacist dispense the lowest cost multi-source drug product that the pharmacy has in stock which meets the medical needs of the beneficiary. At the same time State law made it a misdemeanor for a pharmacist to substitute if human health or life were endangered. The extent of compliance with the Medi-Cal substitution requirement is unknown, but probably has been negligible.

Effective May 1, 1976 "a pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity and dosage form, and of the same generic type...," provided the prescriber does not prohibit it and that the customer is notified of the substitution. 1/ The law applies to all drug buyers, not just Medi-Cal. There has been a trend to similar substitution laws in other states.

Other factors whose impact may soon be to reduce drug prices by increasing the use of lower cost substitutes are:

<sup>1/</sup>Business and Professions Code, Section 4047.6.